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K001903
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APPENDIX D

510(k) Summary

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510(k) Summary
Neotonus, Inc.
NeoControl® Pelvic Floor Therapy System

1. Sponsor

Neotonus, Inc.
835 Franklin Court SE, Suite B
Marietta, GA 30067

Contact Person: Tony J. Morris, President
Date Prepared: June 21, 2000

2. Device Name

Proprietary Name:	NeoControl® Pelvic Floor Therapy System
Common/Usual Name:	Pelvic floor stimulator
Classification Name:	Nonimplanted electrical continence device

3. Intended Use

The NeoControl® Pelvic Floor Therapy System is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women.

4. Purpose of 510(k)

The NeoControl® Pelvic Floor Therapy System, formerly known as the Neotonus Model 1000 Magnetic Stimulator, was previously found to be substantially equivalent to the InCare Pelvic Floor Therapy System in K973096. The 510(k) Summary for K973096 contains a technical description of the NeoControl and a discussion of the basis for that substantial equivalence decision. This 510(k) premarket notification is for the purpose of removing the contraindication against use of the NeoControl in patients with a history of cardiac arrhythmia and replacing it with a statement to use caution when treating such patients.

5. Basis For Substantial Equivalence

Magnetic field test results presented in K973096 demonstrate that the NeoControl stimulus decays exponentially with distance from the coil, and that the strength of the field reaching the heart is well below the threshold for cardiac stimulation as established by the scientific literature. Several predicate magnetic stimulators used for peripheral nerve stimulation are not contraindicated for use in patients with cardiac arrhythmia, even though they emit stronger magnetic fields and can be used in closer proximity to the heart as compared to the NeoControl. Finally, the MS-101, a magnetic stimulator manufactured by Neotonus for muscle stimulation, is not contraindicated against use in patients with cardiac arrhythmia. Although the MS-101 has a somewhat lower field strength for targeting a smaller tissue area, it is used in closer proximity to the heart than the NeoControl. All of the above reasons support the substantial equivalence of the NeoControl with respect to the requested labeling changes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2000

Neotonus, Inc.
c/o Sheila Hemeon-Heyer, J.D., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K001903
NeoControl® Pelvic Floor Therapy System
Dated: June 21, 2000
Received: June 22, 2000
Regulatory Class: II
21 CFR 876.5320/Procode: 78 KPI

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001903

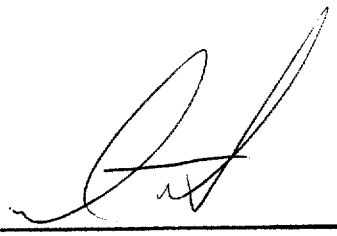
Device Name: NeoControl® Pelvic Floor Therapy System

Indications For Use:

The NeoControl® Pelvic Floor Therapy System is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 001903

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)